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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,372

04/19/2006

Mara Rossi

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO Box 142950  
GAINESVILLE, FL 32614

EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

01/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/576,372	ROSSI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-25,32-34 and 38-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25,32-34 and 38-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/05/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2008 has been entered.

### ***Information Disclosure Statement***

The applications No. 11/916,087 (filed 11/20/2007) and No. 11/915,453 (filed 11/26/2007) have not considered these 2 applications, since these applications have been published as US2008/0200658 for application No. 11/916,087 and US2008/0199913A1 for application 11/915,453. The Examiner has listed these 2 published applications of the PTO-892.

### ***Status of Application, Amendments and/or Claims***

The amendment of 30 October 2008 has been entered in full. Claims 1-21, 26-31, and 35-37 have been cancelled. Claim 46 has been newly added.

Claims 22-25, 32-34, and 38-46 are under examination.

Please note that the status of claims 32-24, 40, 41, and 45 are disclosed in the conclusion of the present office action.

### **Rejection Maintained**

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.  
This application currently names joint inventors.

In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-25, 38, 39, 42, 43, and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti E. (2002, TRENDS in Biotechnology, Volume 20, Issue 8, pages 333-337) in view of Xiang et al. (2001, The Journal of Biological Chemistry, Volume 276, Issue 20, pages 17380-17386) and Burton et al. (1998, Journal of Chromatography A, Volume 814, pages 71-81).

At page 7 of the response, Applicants argue that the Patent Office has failed to establish that there was a recognized problem or need in the art to solve a problem that would have motivated one to even try to purify IL-18BP using hydrophobic charge induction chromatography, that this solution was one of a finite number of identified, predictable solutions to the recognized need or problem or that one skilled in the art would have had a reasonable

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expectation of success in purifying IL- 18BP using hydrophobic charge induction chromatography.

In addition, Applicants note that the cited reference does not teach that this segment of the mature IL- 18BP is an Ig domain; rather, 60% of human IL- 18BP resembles an Ig domain. Finally, the cited reference indicates that the predicted Ig domain of IL-18BP has only about 25% amino acid sequence identity with a similar domain within the IL-1 receptor (page 17380, column 2, first full paragraph) and the cited teaching provides no guidance as to the degree of similarity the IL- 18BP has with immunoglobulin molecules or domains thereof.

Applicants' arguments are not persuasive. The Examiner has provided sufficient information regarding the problem of isolating IL-18BP by providing 2 references (Boschetti E. and Xiang et al.) used in the previous office action and has added a new reference by Burton et al. (Hydrophobic Charge Induction Chromatography: Salt Independent Protein Adsorption and Facile elution with Aqueous Buffers", Journal of Chromatography a, 1998, pp. 71-81, vol. 814), so that this solution was one of a finite number of identified, predictable solutions to the recognized need or problem or that one skilled in the art would have had a reasonable expectation of success in purifying IL- 18BP using hydrophobic charge induction chromatography.

Although IL-18BP and IL-1 receptor have limited resemblance to an antibody or an IgG, the specification teaches that this technique is widely employed for proteins in general and does not appear to be limited to antibodies. For instance at page 2, line 20, of the specification, Applicants recite that chromatographic systems having a hydrophobic stationary phase have also been widely employed in the purification of proteins and included in this category are hydrophobic interaction chromatography (HIC) and reversed phase liquid chromatography

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(RPLC). Moreover, the reference by Burton et al. indicates that HCIC can be used to purify small proteins that include chymosin, chymotrypsinogen, and lysozyme (Abstract, page 71). The teachings by Burton et al. provide evidence that the technique of HCIC has been successfully used to purify small proteins besides antibodies as disclosed by Boschetti et al. Since IL-18BP is a small protein as well as it resembles an immunoglobulin, it would be obvious for one skilled in the art to use the hydrophobic charge induction chromatography purification process as taught by Boscetti E. (2002) and Burton et al. (1998) for the purification of IL-18BP.

Under *KSR*, it's now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated. When there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try may show that it was obvious under § 103 (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, \_\_\_, 82 USPQ2d 1385, 1397 (2007)).

Therefore, in view of *KSR* and in combination with the fact hydrophobic charge induction chromatography (HCIC) represents an improvement towards achieving the ideal situation in the design of an antibody-selective sorbent and the operating characteristics of the sorbents permits significant process simplification compared with traditional approaches, and also a good level of specificity (Boschetti et al., 2002, page 333, right column 2<sup>nd</sup> full paragraph), it would be reasonable to use the method of Boschetti et al., (2002) for the purification of IL-18BP.

In addition, the reference by Xiang et al. discloses that IL-18BP has structural characteristics that are similar to an immunoglobulin IgG by reciting "that approximately 60% of the mature human IL-18BP resembles an immunoglobulin (IgG) domain that includes a highly conserved pair of cysteines and tryptophan residues" and by comparing it to another protein with similarities to immunoglobulin such as only about 25% amino acid sequence identity with a similar domain within the IL-1 receptor. Xiang et al. recite that the resemblance to IL-18BP is

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appropriate because IL-18 itself is not an immunoglobulin because the structural similarities of IL-18BP to an IgG disclosed by Xiang et al. can be utilized to purify it with methods used for the purification of immunoglobulin.

### **Conclusion**

Claims 22-25, 38, 39, 42, 43, and 44 are not allowed. In addition, claims 32-34, 40, 41, 45, and 46 are not allowed, since they are dependent on rejected claims.

### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
January 12, 2009

/Robert Landsman/  
Primary Examiner, Art Unit 1647